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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,862	04/06/2006	Micheal J. Pugia	017191.0049	5494

47670 7590 04/27/2007
KELLEY DRYE & WARREN LLP
400 ATLANTIC STREET
13TH FLOOR
STAMFORD, CT 06901

EXAMINER	
WEN, SHARON X	
ART UNIT	PAPER NUMBER
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,862	PUGIA ET AL.	
	Examiner	Art Unit	
	Sharon Wen	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-12 and 14-32* is/are pending in the application.

4a) Of the above claim(s) *1 and 3-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 14-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/30/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 12 and 14-32 and species election of monoclonal antibody Mab 421-3G5 and the immunoassay ELISA in the reply filed on 02/12/2007 is acknowledged.

The traversal is on the ground(s) that the general inventive concept is not lacking because: 1) the present claims are not directed broadly to the use of monoclonal antibodies for detecting UTI, but to the use of antibodies secreted by hybridomas produced from purified uristatin; 2) monoclonal antibodies from uristatin are believed to be novel; and 3) monoclonal antibodies of the present claims are raised from a lower molecular weigh UTI where as the reference monoclonal antibodies were raised from higher molecular weight UTIs or pro-inhibitor. This is not found persuasive for the reasons of record and that addressed herein which is reiterated for applicant's convenience:

The present claims are directed to a monoclonal antibody for detecting UTI. By Applicant's own definition, "*UTI means **all** the inhibitors identified as inhibiting the serine proteases...including fragments and variants and aggregates that are capable of inhibition*" (see the instant specification on page 7, line 11-14). Trefz et al. teaches the hybridoma production of monoclonal antibody raised from purified UTI (see page 350, second paragraph). Furthermore, the reference monoclonal antibody detects an epitope located at the HI-30 peptide which is a fragment of UTI (page 350, first paragraph). HI-30 is a fragment of higher molecular weight UTI according to Applicant's definition. As stated above, the present claims read on a monoclonal antibody for detecting all serine proteases including fragments and variants. Therefore, a monoclonal antibody detecting HI-30 and its use to detect UTI anticipate the technical features in the present claims. Taken together the technical feature of the present application does not make a contribution over prior art thus unity of invention does not exist.

The requirement is still deemed proper and is therefore made FINAL.

Upon further consideration, the priort art search has been extended to include monoclonal antibodies ATCC 421-5G8.1A8.5C1 and ATCC 420-5D11.5G8.1E4.

Claims 12, 14-32 are currently under examination as they read on a method of assaying for UTI.

Claims 1 and 3-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group of Invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/12/2007.

Claims 2 and 13 have been canceled.

Priority

2. The domestic priority date of the instant claims is deemed to be the filling date of the provisional application USSN 60/511,835, filed 10/16/2003.

Information Disclosure Statement

3. Applicant's IDS filed 05/30/2006 is acknowledged and has been considered.

Specification

4. Applicant is invited to review and correct all spelling, TRADEMARK, and like errors (e.g. claim 16, "dtected"; Table 3, "Bikuinin")

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademark is permissible in patent application, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112, second paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims **12, 14-23** and **25** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The terms "strongly detected" and "binds strongly" in claims **15-17** are relative terms which render the claim indefinite. The terms "strongly detected" and "binds strongly" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. The strength of detection or binding of the recited UTIs in the present claim by the monoclonal antibodies has been rendered infinite because Applicant fails to set forth a standard for the strength of detection or binding (i.e. what is detected strongly or weakly).

B) Claim **19** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. See MEPE § 2173.05(r). Note the "as defined herein" language which is what makes the claim an omnibus claim.

C) Claim **12** and the dependent claims, **14-23** and **25**, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are the resolution steps such as those recited in claim 24.

D) Claim **25,** which depends from claim 12, recites the limitation "one of said hybridoma". There is insufficient antecedent basis for this limitation in the claim because the phrase "one of said hybridoma" implies that the base claim, claim 12, recites more than one hybridomas. However, claim 12 recited only one hybridoma. Such inconsistency renders claim 25 indefinite.

For the purpose of examination of merits, claim 25 will read on "antibody secreted by said hybridoma".

E) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any New Matter. See MPEP § 714.02 and 2163.06.

Claim Rejections - 35 USC § 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims **24** and **27** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C § 112, paragraph 1 "Written Description" requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January, 2001, See especially page 1106 3rd column).

Regarding the instant claim limitations, the specification does not appear to provide an adequate written description for all UTIs as targets of the claimed monoclonal antibodies for the following reason:

The present claims read on a genus of monoclonal antibodies that bind to a genus of UTIs including "*all the inhibitors identified as inhibiting the serine proteases, including fragments and variants and aggregates that are capable of inhibition*" (e.g. see page 7, Definitions, lines 11-14). However there is a lack of sufficient written description to support the claimed genus of UTIs. Similarly Applicant has not provided a sufficient written description of a monoclonal antibody that selectively binds to such fragment, variant or aggregates of UTIs , because such

monoclonal antibody would not reasonably be expected to be reactive with uristatins, bikunin, AMBK and THP (e.g. see page 22-23, Tables 3-4 of the instant specification). For example, Lederman et al. (Molecular Immunology 28: 1171-1181, 1991; see entire document) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody. Further, Li et al. (PNAS 77: 3211-3214, 1980; see entire document) disclose that dissociation of immunoreactivity from other biological activities when constructing analogs (see entire document). Therefore, the specification does not provide for sufficient written description to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, Applicant had possession of antibodies reactive with all fragments, variants and aggregates of UTIs, other than the monoclonal antibodies reactive with uristatins, bikunin, AMBK and THP.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.) Consequently, Applicant was not in possession of the instant claimed invention. See *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision. (See page 1115.)

9. Claims **24** and **27** are further rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for monoclonal antibodies having preferential binding to uristatins, Bikunin, AMBK and THP (e.g. see page 22-23, Tables 3-4 of the instant specification), does <u>not reasonably provide enablement</u> for any monoclonal antibody that has specificity for <u>all</u> UTIs which include "*all the inhibitors identified as inhibiting the serine proteases, including fragments and variants and aggregates that are capable of inhibition*" (e.g.

see page 7, Definitions, lines 11-14). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claims 24 and 27 are directed to a method of assaying for UTIs using a first monoclonal antibodys that bind to all UTI and a second antibody that binds to a subset of all the UTIs; and then subtract what is bound by the second antibody from the first antibody to measure a UTI detected by the first but not by the second antibody. The present claims read on a genus of antibodies binding to all UTIs including fragments, variants, and aggregates. However the instant specification, at the time the application was filed, disclosed only three monoclonal antibodies having preferential bindings to the uristatins, Bikunin, AMBK and THP. The structures of other fragments, variants and aggregates, which the claims read on, are unpredictable. The insufficient guidance provided by the Applicant impose an undue amount of experimentation to evaluate the binding capability of all species of the genus of antibodies for all the species of UTIs claimed herein. Therefore the specification does not enable a skilled artisan to practice the claimed invention at the time the application was filed.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary, the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

10. Claims **12** and **13-32** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting UTIs in a biological sample using monoclonal antibodies, does not reasonably provide enablement for correlating the result of detection with a disease associated with the measured UTIs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims relate to a method for assaying for UTIs in a biological samples; the only use for this assay as disclosed by Applicant is for diagnosing disease. The method includes the steps of performing an assay on a blood or urine sample with monoclonal antibodies that bind

preferentially to certain fragment or species of UTI and provide a detectable signal with reporter molecules that are related to the presence or amount of these UTI species. The UTIs determined from the assay method are then correlated with a disease associated with the measured distribution of UTIs.

Given the teaching of the claims and specification, the nature of the present invention relates to diagnosing a plurality of diseases including any bacterial infection and inflammatory disorders or other maladies such as malignant tumors, kidney disease, myocardial infarction, lung emphysema, surgical trauma, and kidney stones (see specification on page 1, paragraph 1). In Applicant's disclosure, reference by Trefz et al. were mentioned to demonstrate detecting ITI, a precursor of UTI, correlated to lung disease (page 3, last paragraph). In addition, U.S. Patent 6,242,197 by Pauashvili et al. also teaches the use of UTI for diagnosis of the onset of AIDS (see title). In the present application, it is suggested that certain fragments or species of UTI are correlated to certain diseases (see claims 24 and 27, and page 26, second paragraph of specification). However, the instant specification does not provide sufficient guidance on how to correlated which species of UTIs detected from the assay with which disease. Though the state of the art teaches UTI can be a diagnostic marker for certain diseases (e.g. lung diseases and AIDS), insufficient teaching of the present applicant, at the time it is filed, does not enable a person of skill to use the present assay to diagnose the plurality of diseases disclosed by the Applicant. For example, Merck Manual teaches the diagnosis of myocardial infarction include ECG and analysis of cardiac markers (see Merck Manual [online]. Copyright © 1995-2007 Merck & Co., Inc., Whitehouse Station, NJ, USA. [retrieved on 4/18/2007]. Retrieved from the Internet:< http://www.merck.com/mmpe/sec07/ch073/ch073c.html#sec07-ch073-ch073c-664>. Acute Coronary Syndromes (ACS); Diagnosis). The manual does not teach any UTI being a marker for myocardial infarction. Taken together, the lack of sufficient guidance provide by Applicant, one of skill is not enabled to use the claimed method to diagnose any disease.

One cannot extrapolate the measurement of UTI to the scope of the claims because said teachings represent insufficient guidance and objective evidence to predictably enable the use of the claimed invention. One skilled in the art would recognize that it is not possible to conclude anything about the use of a given method as a diagnostic tool based on the use of assaying for UTI. Likewise, one skilled in the art would recognize that it is not possible to conclude that the

presence of UTI can be used for determining plurality of diseases (for example, diagnosing myocardial infarction) based on the fact that the presence of UTI may be indicative of disease.

The courts have stated that "tossing out the mere germ of an idea does not constitute enabling disclosure." Genentech, 108, F.3d at 1366 (quoting *Brenner v. Manson*, 383 U.S. 519, 536 (1996) (stating, in context of the utility requirement, that a "patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion"). "[R]easonable detail must be provided in order to enable members of the public to understand and carry out the invention." Id.

In the instant case, such reasonable detail is lacking. The specification lists a number of different species and fragments of UTIs and suggests that a differential detection of the different fragments is important for clinical settings (see specification on page 25). However, the specification fails to identify which fragments or species of UTI are associated with certain disease state. The specification further fails to disclose what levels of each fragment or species would be indicative of a particular disease.

Although the specification outlines art-recognized methodology using monoclonal antibodies having preferences for certain UTIs to open the possibility of distinguishing certain diseases or other medical problems with a particular distribution of UTI fragment (specification page 26, paragraph 2), such a general roadmap amounts to an invitation to conduct further research, rather than a specific direction required to enable one of ordinary skill in the art to understand and carry out the invention. Hence, this general outline for how to test and validate the correlation between different fragments or species of UTI and a plurality of diseases fails to constitute an enabling disclosure in light of complexity, unpredictability and laborious nature of validating the correlation of UTI and disease state (discussed further below) and furthermore fails to provide one skilled in the art with any reasonable expectation of success in using any particular combination monoclonal antibodies having preference to a set of UTIs to distinguish amongst a plurality of diseases. The specification sets forth a research plan, not an invention to be practiced.

For example, Bast, Jr. et al. (*Clinical Cancer Research*, 2005, 11:6103-6108) point to the "lengthy process" of assay development and validation and note that many markers that correlate with disease statistically may not prove to be useful clinically (page 6105, right column).

Similarly, LaBaer et al. (*Journal of Proteome Research*, 2005, 4:1053-1059) teaches that crucial validation steps are needed to demonstrate that an identified biomarker is a reliable predictor and also that the process of converting such a biomarker into a practical clinical test is even more daunting (page 1053, paragraph bridging the left and right columns). In addition, Baker (*Nature Biotechnology*, 2005, 23:297-304) speaks to the unpredictability involved in clinically applying biomarkers (page 298, *Walking on Thin Ice*).

In summary, the specification lists a number of species and fragments of UTIs and suggests the use of various monoclonal antibodies that preferentially bind to certain UTIs for diagnosing a disease state amongst a plurality of diseases. However, the specification lacks clinical data validating the various UTIs corresponding to a particular disease state, and fails to disclose specific guidance regarding which specific UTI species or fragments are to be used to diagnose a disease and what levels would be indicative of a specific disease. Taken together with the breadth of the claims and the unpredictability associated with validation of UTI for clinical use, the specification fails to teach the skilled artisan how to make and use the claimed invention in its full scope without further undue experimentation.

11. Claims **14-19, 22-23** and **26-32** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that hybridomas, ATCC 421-3G5.4C5.3B6, ATCC 421-5G8.1A8.5C1 and ATCC 420-5D11.5G8.1E4, are required to practice the claimed invention. As the required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the hybridomas which produce the monoclonal antibodies. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Although applicant has deposited the hybridomas with the ATCC under the Budapest Treaty, there appears no assurances indicated above. Applicant's provision of these assurances would obviate this objection/rejection.

Applicant is reminded of the above and should amend the specification accordingly.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims **12, 20-21** and **25** are rejected under 35 U.S.C. 102(b) as being anticipated by Papuashvili et al. (U.S. Patent 6,242,197, see entire document).

The present claims read on a method of assaying for UTIs from urine or blood with a monoclonal antibody. Papuashvili et al. teach a method to diagnose AIDS by assaying for UTI in body fluids (see column 2, lines 35-60). Specifically, the reference teaches a method for diagnosing the onset of AIDS in a subject comprising collecting a sample of blood or urine and contacting the sample with monoclonal antibody which binds to UTI under immunological reaction (e.g. see claims 1-3).

Though Papuashvili et al is silent on the antibody secreted by a hybridoma, one of ordinary skill would recognize that the monoclonal antibody of the reference is secreted from a hybridoma because it is an inherent property of a monoclonal antibody.

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Conclusion

14. No claim is allowed

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Wen whose telephone number is (571) 270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on (571) 272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Wen, Ph.D.
Patent Examiner

ZACHARIAH LUCAS
PATENT EXAMINER

April 17, 2007